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TITLE: INTRALUMINAL SPECTROSCOPE WITH WALL CONTACTING PROBE

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INTRALUMINAL SPECTROSCOPE WITH WALL-CONTACTING PROBE

FIELD OF INVENTION

The invention relates to spectroscopy, and in particular, to spectroscopes for detecting vulnerable plaques within a wall of a blood vessel.

BACKGROUND

Atherosclerosis is a vascular disease characterized by a modification of the walls of blood-carrying vessels. Such modifications, when they occur at discrete locations or pockets of diseased vessels, are referred to as plaques. Certain types of plaques are associated with acute events such as stroke or myocardial infarction. These plaques are referred to as "vulnerable plaques." A vulnerable plaque typically includes a lipid-containing pool of necrotic debris separated from the blood by a thin fibrous cap. In response to elevated intraluminal pressure or vasospasm, the fibrous cap can become disrupted, exposing the contents of the plaque to the flowing blood. The resulting thrombus can lead to ischemia or to the shedding of emboli.

One method of locating vulnerable plaque is to peer through the arterial wall with infrared light. To do so, one inserts a catheter through the lumen of the artery. The catheter includes a delivery fiber for illuminating a spot on the arterial wall with infrared light. Various particles in the blood, as well as the arterial wall itself, scatter or reflect much of this light. A small portion of the light, however, penetrates the arterial wall, scatters off structures deep within the wall. Some of this deeply-scattered light re-enters the lumen. This re-entrant light can be collected by a collection fiber within the catheter and subjected to spectroscopic analysis.

In an effort to avoid recovering light scattered from the blood and from the wall surface, the delivery fiber is displaced from the collection fiber. The diameter of the catheter must therefore be large enough to accommodate the two fibers and the gap that separates them.

SUMMARY

The invention is based on the recognition that by collecting scattered light directly from an intraluminal wall, one avoids scattering that results from propagation of light through blood. As a result, it is no longer necessary to provide separate collection and delivery fibers. Instead, only a single fiber is necessary.

In one aspect, the invention includes a spectroscope for detecting vulnerable plaque within a lumen defined by an intraluminal wall. The spectroscope includes a probe having one or more optical fiber extending therethrough, and an atraumatic coupler in communication with the optical fiber(s). The coupler is configured to atraumatically contact the intraluminal wall. The spectroscope also includes a light source in optical communication with the fiber for illuminating the wall; and a detector in optical communication with the fiber for detecting light from within the wall.

In one embodiment, the probe includes a jacket enclosing the fiber. The jacket can be a coil-wire wound into a coil-wire jacket, with or without a variable diameter coil wire.

In other embodiments, the probe resiliently assumes a preferred shape. Examples of preferred shapes include a bow, an arc, a catenary, or a portion thereof.

The atraumatic coupler can be on the distal end of the probe. Embodiments of this type include those in which the atraumatic coupler is a lens attached to the distal tip of the optical fiber. Additional embodiments include those in which the atraumatic coupler is integral with the optical fiber, as for example where a distal tip of the optical fiber forms part of the atraumatic coupler.

The atraumatic coupler can also be along a side of the probe. Examples of such couplers include those having a window along a side of the probe, and a beam re-director providing optical communication between the window and a distal tip of the fiber. Other examples include those in which a distal face of the optical fiber provides optical communication with the window.

The invention optionally includes a cannula through which the probe passes. The cannula can include walls forming a channel conformal with the cannula through which the probe passes. In these embodiments, the probe can be steered toward the wall by providing tapered or flared distal end having an opening facing toward or away from a longitudinal axis of the cannula.

Other embodiments include those having a hub to which a distal end of the probe is attached, and those in which a cannula is provided for the hub and probe to pass through. In these embodiments, the probe can be one that resiliently assumes a bow shape for contacting the intraluminal wall at a point of inflection thereof. A coupler can then be placed at the point of inflection.

In another aspect, the invention includes a spectroscope having a cannula and a plurality of probes extending through the cannula. Each probe has an optical fiber extending therethrough, and an atraumatic coupler in communication with the optical fiber. The coupler is configured to atraumatically contact the intraluminal wall.

Some embodiments include a spacer ring attached to each of the probes for maintaining the positions of the probes relative to each other. Others include a hub attached to a distal end of each of the probes.

Another aspect of the invention is a method of detecting vulnerable plaque within an intraluminal wall. The method includes placing an atraumatic light coupler in contact with the intraluminal wall and passing light through the intraluminal wall by way of the atraumatic light coupler. Light from within the intraluminal wall is then recovered by way of the atraumatic coupler. This light is then provided to a processor for analysis to identify the presence of a vulnerable plaque.

In some practices of the method, placing an atraumatic light coupler in contact with the intraluminal wall includes placing a distal end of a probe in contact with the intraluminal wall. In other practices of the invention, it is a side of the probe that is placed in contact with the intraluminal wall.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic diagram of a spectroscope for identifying vulnerable plaque.

FIG. 2 is a schematic view of a probe in contact with the arterial wall.

FIG. 3 is a cross-section of the probe of FIG. 2.

FIGS. 4A-G are exemplary atraumatic light-couplers for an optical fiber.

FIGS. 5A-F are schematic views of single-probe spectroscopes.

FIGS. 6A-F are schematic views of multi-probe spectroscopes.

FIG. 7A is a schematic view of a probe emerging from a cannula having a tapered distal end.

FIG. 7B is a schematic view of a probe emerging from a cannula having a flared distal end.

FIGS. 8A-8F are schematic views of multi-probe spectroscopes in which the atraumatic light-couplers are along the sides of the probes.

FIGS. 8G-K are schematic views of spectroscopes in which the probes are integrated into the cannula.

FIGS. 9A-D are views of exemplary atraumatic light-couplers for the probes in FIGS. 8A-H.

DETAILED DESCRIPTION

FIG. 1 shows a spectroscope **10** for identifying vulnerable plaque **12** in an arterial wall **14** of a patient. The spectroscope features a probe **16** to be inserted into a selected artery, e.g. a coronary artery, of the patient. An optical fiber **18** extends between a distal end and a proximal end of the probe **16**.

In a first embodiment, shown in FIGS. 2-3, an atraumatic light-coupler **24** at the distal end of the probe **16** rests on a contact area **26** on the arterial wall **14**. When disposed as shown in FIG. 2, the atraumatic light-coupler **24** directs light traveling axially on the fiber **18** to the contact area **26**. After leaving the atraumatic light-coupler **24**, this light crosses the arterial wall **14** and illuminates structures **28** behind the wall **14**. These structures **28** scatter some of the light back to the contact area **26**, where it re-emerges through the arterial wall **14**. The atraumatic light-coupler **24** collects this re-emergent light and directs it into the fiber **18**.

Along a proximal section of the probe **16**, as shown in FIG. 3, a rigid tube **38** encasing the fiber **18**, enables the probe **16** to be pushed through the artery. Along a central and distal section of the probe **16**, a coil wire **44** wound into a flexible coil-wire jacket **46** encases the fiber **18**.

The coil wire **44** has a constant diameter along the central section. Along the distal section of the probe **16**, the diameter of the coil wire **44** becomes progressively smaller. As a result, the distal section of the probe **16** is more flexible than its central section. This enhanced flexibility enables the distal section to follow the contour of the wall **14** without exerting unnecessary force against it.

The atraumatic light-coupler **24** can be formed by attaching a lens assembly to a distal tip of the fiber **18**, as shown in FIGS. 4A, 4B, and 4E, or by attaching a rounded glass tip to an angled fiber, as shown in FIGS. 4F-G. Alternatively, the atraumatic light-coupler **24** can be made integral with the fiber **18** by smoothing any sharp edges at its

distal tip, as shown in FIGS. 4C-D.

In either case, the atraumatic light-coupler **24** can include a spherical lens, as shown in FIG. 4A, or a hemispherical lens, as shown in FIG. 4B. The atraumatic light-coupler **24** can also include more than one lens element, as shown in FIG. 4E.

Alternatively, the atraumatic light-coupler **24** can be integral with the fiber **18.** For example, the distal tip of the fiber **18** can be formed into a plane having rounded edges and oriented at an angle relative to the plane of the fiber cross-section, as shown in FIG. 4D, or into a hemisphere, as shown in FIG. 4C.

Referring back to FIG. 1, one using the spectroscope **10** positions the atraumatic light-coupler **24** against the arterial wall **14** and engages a motor **49** coupled to the probe **16**. The motor **49** rotates the probe **16** at a rate between approximately 1 revolution per second and 400 revolutions per second. This causes the atraumatic light-coupler **24** to trace a path around the inner circumference of the arterial wall **14**. As it rotates, the atraumatic light coupler **24** redirects light placed on the fiber **18** by a light source **50**, such as a near infrared light source, to the contact area **26**. At the same time, the atraumatic light-coupler **24** collects light re-emerging from the contact area **26** and directs it into the fiber **18**, which then guides it to a photo-detector **52**.

The photo-detector **52** provides an electrical signal indicative of light intensity to an analog-to-digital ("A/D") converter **54**. The A/D converter **54** converts this signal into digital data that can be analyzed by a processor **56** to identify the presence of vulnerable plaque hidden beneath the arterial wall **14**.

In a second embodiment, shown in FIGS. 5A-C, a probe housing **59** extends through a cannula **60** parallel to, but radially displaced from a longitudinal axis thereof. A probe **16** is kept inside the probe housing **59** until it is ready to be deployed. Extending along the longitudinal axis of the cannula **60** is a guide-wire housing **61** forming a guide-wire lumen through which a guide-wire **63** extends.

The probe **16** can be an optical fiber made of glass or plastic, or a bundle of such fibers. In one embodiment, the probe includes a bundle of 25 optical fibers, each .005

millimeters in diameter. The fiber(s) can be exposed, coated with a protective biocompatible layer and/or a lubricious layer such as polytetrafluoroethylene ("PTFE"), or encased in a coil-wire jacket. The optional coating or jacket around the fiber(s) could be round, and hence bendable in all directions, or flat, so as to suppress bending in undesired directions.

The distal tip of the optical fiber **18** is capped by any of the atraumatic light-couplers **24** discussed above. When the distal end of the cannula **60** is just proximal to contact area **26**, the probe **16** is pushed distally so that its distal tip extends past the distal end of the cannula **60**. Alternatively, the probe **16** remains stationary while the cannula **60** is retracted, thereby exposing the probe **16.**

The probe **16** is pre-formed so that a natural bend urges it outward, away from the axis of the cannula **60.** As a result, when the probe **16** is extended out its housing **59** and beyond the distal end of the cannula **60**, this natural bend places the atraumatic light-coupler **24** of the fiber **18** in contact with the arterial wall **14** distal to the cannula **60**. The probe **16** is then rotated so that the atraumatic light-coupler **24** traces out a circular contact path along an inner circumference of the wall **14**, as shown in FIGS. 5A and 5C**.**

A variety of ways are known for pre-forming a probe **16**. For example, the probe **16** can be heated while in the desired shape. Or a coating over the fiber within the probe **16** can be applied and cured while the fiber is in the desired shape.

In a third embodiment, shown in FIGS. 5D-F, the cannula **60** has a proximal section **88** and a distal section **90** separated from each other by a circumferential gap **92**. A guide wall **94** forms a truncated cone extending distally from a truncated end joined to the guide-wire housing **59** to a base joined to the distal section **90** of the cannula **60**. The guide wall **94** thus serves to maintain the position of the proximal and distal sections **88**, **90** of the cannula **60** relative to each other while preserving the circumferential gap **92** all the way around the cannula **60**.

In use, the probe **16** is extended distally toward the guide wall **94,** which then guides the probe **16** out of the circumferential gap **62**. As was the case with the second

embodiment (FIGS. 5A-C), the natural bend of the probe **16** urges the atraumatic tip **24** into contact with the arterial wall **14**. Once the probe's atraumatic tip **24** contacts the wall **14**, the probe **16** is rotated as shown in FIGS. 5D-F so that the atraumatic tip **24** sweeps a circumferential contact path on the arterial wall **14**.

In a fourth embodiment, shown in FIGS. 6A-C, several probes **16** of the type discussed above in connection with FIGS. 5A-F pass through the cannula **60** at the same time. Optional spacer rings **64** are attached to the probes **62** at one or more points along their distal sections. The spacer rings **64** can be silicon webbing, plastic, Nitinol, or any other biocompatible material.

When deployed, the spacer rings **64** are oriented so as to lie in a plane perpendicular to the longitudinal axis of the cannula **60**. The spacer rings **64** thus maintain the relative positions of the probes **16** during scanning of the wall **14**. A multi-probe embodiment as shown in FIGS. 6A-C enables most of the circumference of an arterial wall **14** to be examined without having to rotate the probes **16**.

In a fifth embodiment, shown in FIGS. 6D-F, the cannula **60** is as described in connection with the third embodiment (FIGS. 5D-F). The difference between this fifth embodiment and the third embodiment (FIGS. 5D-F) is that in the third embodiment, a single probe **16** extends through the circumferential gap **92,** whereas in this fifth embodiment , several probes **16** circumferentially offset from one another extend through the circumferential gap **92**. As a result, in the third embodiment, it is necessary to rotate the probe **16** to inspect the entire circumference of the arterial wall **14**, whereas in the fifth embodiment, one can inspect most of the arterial wall **14** circumference without having to rotate the probes **16** at all.

In a sixth embodiment, a cannula **60** has a tapered distal end **68**, as shown in FIG. 7A, or a flared distal end **70**, as shown in FIG. 7B. A channel **72** formed in the inner wall of the cannula **60** has a bend **74** proximal to an opening **76** at the distal end. This opening **76** defines a surface whose normal vector has both a radial component and an longitudinal component.

One operating the embodiments of FIGS. 7A and 7B pushes the probe **16** through the channel **72**, which then guides it toward the opening **72**. As the probe **16** exits the channel **72,** it proceeds in the direction of the normal vector until its atraumatic light-coupler **24** contacts the arterial wall **14**. In this case, the probe **16** need not be pre-formed to have a preferred shape since the channel **72** guides the probe **16** in the correct direction for reaching the wall **14**.

In a seventh embodiment, shown in FIGS. 8A-B, a plurality of probes **16** passes through a cannula **60**. The distal ends of the probes **16** are attached to anchor points circumferentially distributed around a hub **78**. The hub **78** is coupled to a control wire **80** that enables it to be moved along the longitudinal axis of the cannula **60** to either deploy the probes **16** (FIG. 8A) or to retract the probes **16** (FIG. 8B). However, in other embodiments, the hub **78** remains stationary and it is the cannula **60** that is moved proximally and distally to either deploy or recover the probes **16**.

The probes **16** are pre-formed to bow outward as shown in FIG. 8A so as to contact the arterial wall **14** at an intermediate point between the hub **78** and the cannula **60**. Optional spacer rings **64**, like those discussed in connection with FIGS. 6A-C, are attached to the probes **16** at one or more points along their distal sections to maintain their relative positions. In this seventh embodiment, the atraumatic light-coupler **24** includes a side-window **82** located at the intermediate point. The side window **82** faces radially outward so that when the probe **16** is fully deployed, the side window **82** atraumatically contacts the arterial wall **14.**

An atraumatic light-coupler **24** for placement along the side of the probe **16** includes a right-angle reflector **84**, such as a prism or mirror, placed in optical communication between the fiber **18** and the side window **82**, as shown in FIG. 9B. Alternatively, an air gap **86** is placed in optical communication between the tip of an angle polished fiber **18** and the side-window **82**, as shown in FIG. 9A.

FIGS. 9C-9D shows additional examples of atraumatic light-couplers **24** for placement along the side of the probe **16.** In these examples, the side window **82** is formed by a portion of the fiber's cladding that is thin enough to allow passage of light.

The side window **82** can be left exposed, as shown in FIG. 9C, or a diffraction grating **85** can be placed in optical communication with the side window **82** to further control the direction of the beam, as shown in FIG. 9C.

When the hub **78** and the cannula **60** are drawn together, as shown in FIG. 8B, they can easily be guided to a location of interest. Once the hub **78** and cannula **60** reach a location of interest, one either advances the hub **78** or retracts the cannula **60**. In either case, the probes **16** are released from the confines of the cannula **60,** as shown in FIG. 8A. Once free of the radially restraining force applied by the cannula's inner wall, the probes **16** assume their natural shape, bowing outward, as shown in FIG. 8B, so that their respective side-windows **82** atraumatically contact the arterial wall **14**. The atraumatic light-couplers **24** guide light from the light source **50** through the side windows **82**. At the same time, the atraumatic light-couplers **24** recover re-emergent light from the wall **14** through the side windows **82** and pass it into the fibers **16**, which guide that light to the photo-detector **52**.

When the examination of the wall **14** is complete, the hub **78** and cannula **60** are brought back together, as shown in FIG. 8B, and the probes **16** are once again confined inside the cannula **60**.

In an eighth embodiment, shown in FIGS. 8C-D, the cannula **60** has a proximal section **88** and a distal section **90** separated by a circumferential gap **92**, as described in connection with the third embodiment (FIGS. 5D-F) and the fifth embodiment (FIGS. 6D-F). Unlike the third and fifth embodiments, in which the distal tips of the probes **16** atraumatically contact the wall **14**, in the eighth embodiment the distal tips of the probes **16** are attached to a hub **78** at the distal section **90** of the cannula **60**. Like the probes **16** of the seventh embodiment, the probes **16** of the eighth embodiment have side windows **82** at intermediate points for atraumatically contacting the arterial wall **14**. An actuator (not shown) is mechanically coupled to selectively apply tension to the probes **16**. When the probes **16** are under tension, they lie against the distal section **90** of the cannula **60**, as shown in FIG. 8D. When probes **16** are relaxed, they spring radially outward, away from

the distal section **90**, enough so that the side windows **82** at the intermediate sections atraumatically contact the arterial wall **14**.

In use, the cannula **60** is guided to a region of interest with the probes **16** placed under tension. The probes **16** are thus drawn against the cannula **60**, as shown in FIG. 8B. Once at the region of interest, the tension is released, and the probes **16** spring radially outward, as shown in FIG. 8A, so that the side windows **82** atraumatically contact the wall **14**. After data collection, the probes **16** are again placed under tension to draw them back against the cannula **60**, as shown in FIG. 8B.

In the seventh and eighth embodiments, a particular probe **16** emerges from the cannula **60** at an exit point and re-attaches to the hub **78** at an anchor point. In a cylindrical coordinate system centered on the axis of the cannula **60**, the exit point and the anchor point have different axial coordinates but the same angular coordinate. However, as FIGS. 8E and 8F illustrate, this need not be the case.

FIG. 8E shows a ninth embodiment in which a cannula **60** has a plurality of exit holes **96** and a corresponding plurality of entry holes **98**. Each probe **16** exits the cannula **60** through an exit hole **96** and re-enters the cannula **60** through an entry hole **96** that is circumferentially offset from its corresponding exit hole. This results in the helical arrangement shown in FIG. 8E. The extent of the circumferential offset defines the pitch of the helix.

The distal ends of the probe **16** are attached to a hub **78** (not shown) inside the cannula **60**. Each probe **16** has a side window **82** between the exit hole and the corresponding entry hole. A control wire **80** within the cannula **60** (not shown) deploys the probes **16**, as shown, or retracts them so that they rest against the exterior of the cannula **60**. A guide-wire **63** passing through the cannula **60** and exiting out the distal tip thereof enables the cannula **60** to be guided to a region of interest.

FIG. 8F shows a tenth embodiment in which a cannula **60** has a distal section **88** and a proximal section **90**. The proximal and distal sections of the cannula **60** surround a central shaft **100** having an exposed portion **102**. Probes **16** extend axially through a gap

between the shaft and the cannula **60**. The probes **16** are anchored at their distal ends at circumferentially displaced anchor points on a hub **78** attached to the shaft **100**. The circumferential offset causes the helical configuration of the probes **16** in FIG. 8F. The extent of this circumferential offset defines a pitch of the helix.

An actuator (not shown) selectively applies tension to the probes **16**. When the probes **16** are under tension, they retract against the exposed portion **102** of the central shaft **100**. When the probes **16** are relaxed, they assume the configuration shown in FIG. 8F, in which they spring radially outward from the exposed portion **102** of the central shaft **100** so that their side windows **82** atraumatically contact the arterial wall **14**.

In the embodiments described thus far, the probes **16** and the cannula **60** have been separate structures. However, the probes **16** can also be integrated, or otherwise embedded in the cannula **60**. In this case, portions of the cannula **60** extend radially outward to contact the arterial wall **14**.

FIGS. 8G and 8H show an eleventh embodiment in a deployed and retracted state, respectively. The eleventh embodiment includes slots **104** cut into the wall of the cannula **60** enclosing an internal shaft **100**. Pairs of adjacent slots **104** define probe portions **16** of the cannula **60**. The probe portions **16** buckle outward when the distal tip of the cannula **60** is pulled proximally, as shown in FIG. 8G. When the distal tip of the cannula **60** is extended, the probe portions **16** lay flat against the shaft **100**, as shown in FIG. 8H.

Each probe portion **16** has a side window **82** for atraumatically contacting the wall **14** when the probe portion **16** is deployed. The side window **82** is in optical communication with an atraumatic coupler **24**. An optical fiber embedded within the wall of the cannula **60** provides an optical path to and from the atraumatic coupler **24**.

FIGS. 8I-J show a twelfth embodiment in a deployed and retracted state. The twelfth embodiment includes slots **104** cut into the wall of the cannula **60** enclosing an internal shaft **100**. Unlike the slots **104** in the eleventh embodiment, the slots **104** in the twelfth embodiment extend all the way to the distal tip of the cannula. Pairs of adjacent slots **104** define probe portions **16** of the cannula **60**.

As shown in the cross-section of FIG. 8K, the cannula **60** includes radially-inward projections **106** forming a throat **110**. The shaft **100** has a bulbous portion **112** distal to the throat **110** and a straight portion **114** extending proximally through the throat **110** to join the bulbous portion **112.** The probe portions **16** are biased to rest against the bulbous portion **112** of the shaft **100**, as shown in FIG. 8I. When the shaft **100** is drawn proximally, the bulbous portion **112** wedges against the projections **106**. This forces the probe-portions **16** to pivot radially outward, as shown in FIG. 8J.

Each probe portion **16** has an atraumatic coupler **24** at its distal tip for atraumatically contacting the wall **14** when the probe portion **16** is deployed. An optical fiber embedded within the wall of the cannula **60** provides an optical path to and from the atraumatic coupler **24**.

OTHER EMBODIMENTS

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.